P04782

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 753 324 A1

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
15.01.1997 Bulletin 1997/03

(51) Int Cl.6: A61N 1/365

(21) Application number: 96850112.2

(22) Date of filing: 14.06.1996

(84) Designated Contracting States:
DE ES FR GB IT

(30) Priority: 10.07.1995 SE 9502534

(71) Applicant: Pacesetter AB
171 95 Solna (SE)

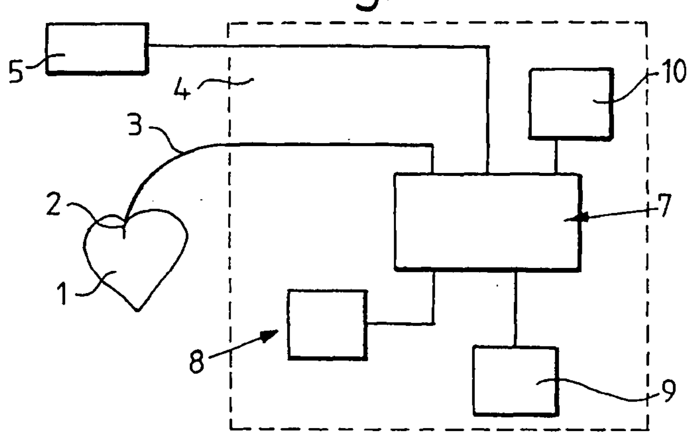
(72) Inventor: Ekwall, Christer
163 57 Spanga (SE)

(74) Representative: Hammar, Ernst
H. Albihns Patentbyra AB,
P.O. Box 3137
103 62 Stockholm (SE)

(54) Heart stimulator with variable stimulation pulse energy

(57) The invention relates to a heart stimulator (4), for the stimulation of a heart (1), comprising a pulse generator (8) periodically producing stimulation pulses, at least one electrode means (3) connectable to said pulse generator (8) and to the heart (1) for transmitting said pulses to said heart (1) and respiration monitoring means (5) for monitoring the respiration of the human being, wherein the heart stimulator (4) adapts the energy to be delivered in a stimulation pulse in response to the information acquired by the respiration monitoring means (5) which indicate the stage in the human being's respiration cycle that the human being has reached.

Fig. 2



EP 0 753 324 A1

Description

Background of the invention

The present invention relates to heart stimulators, for the stimulation of the hearts, comprising a pulse generator periodically producing stimulation pulses and at least one electrode means connectable to said pulse generator and to the heart for transmitting said pulses to said heart.

Pacemakers are known which measure the respiration rate of the user and vary the interval between stimulation pulses according to the respiration rate such that an increase in the respiration rate, which generally corresponds to an increase in the activity of the user, causes an increase in the stimulation pulse rate. An example of such a pacemaker is shown in US-A 4 757 815.

Further pacemakers are known which attempt to reduce to a minimum the energy delivered in each stimulation pulse in order to extend the life of the pacemaker battery. These pacemakers, known as Autocapture pacemakers, use adjustment algorithms to determine the minimum stimulation energy level. In order to ensure capture, the stimulation pulse energy is then set at a value which is 50%-100% greater then the minimum stimulation pulse energy. However, the respiration of the user interferes with the correct functioning of these units by continuously varying the shape of the chest which causes temporary, non-linear variations in the stimulation impedance. This means that the stimulation pulse energy required for successful capture varies during the breathing cycle. Current algorithms do not take into account at which point in the respiration cycle the stimulation pulse occurs. This means that occasionally even a stimulation pulse containing pulse energy which is 100% greater than the minimum stimulation pulse energy is insufficient to result in a capture. In this case, current algorithms automatically increase the pulse energy for the next pulse. However, this pulse may be unnecessarily powerful and hence waste energy because it is quite possible that, due to changes in the shape of the chest caused by respiration, the stimulation impedance may have, in the meantime, dropped to a lower value.

It is possible to measure the stimulation impedance directly, for example by transmitting a pulse of sufficiently low amplitude that it cannot stimulate the heart and measuring the strength of the returning signal. However such a method uses energy and is also subject to errors caused by the return signal being masked by noise from normal electrical activity in the user's body.

Summary of the invention

It is an object of the present invention to provide a heart stimulator of the above-mentioned kind which can vary the stimulation pulse energy, in order, for example, to conserve energy, without being subject to errors caused by noise from normal electrical activity in the user's body.

In accordance with the invention, this object is achieved by providing a heart stimulator which monitors the user's respiration cycle to indirectly determine the stimulation impedance and hence to modify the stimulation pulse energy so as to achieve heart stimulation with minimum energy consumption.

Description of the drawings

Figure 1 shows a schematic illustration of chest volume and stimulation impedance amplitude variations and the variation in simulation pulse energy required during the respiration cycle of a heart stimulator user.

Figure 2 is a schematic diagram of a heart stimulator constructed in accordance with the present invention.

Description of the preferred embodiments

Figure 1 shows in a simplified form how the stimulation impedance Is and hence the minimum stimulation pulse energy varies throughout a respiration cycle. In this case stimulation impedance Is is at a maximum when inhalation and hence lung volume Lv is at a maximum and stimulation impedance Is gets smaller in a non-linear manner as air is exhaled and vice versa, and minimum stimulation pulse energy Emin required is proportional to stimulation impedance. Although the variation in stimulation impedance Is is non-linear, it is regular and the stimulation impedances measured at any particular stage or phase angle in consecutive respiration cycles will not vary much if the respiration rate is nearly constant.

Figure 2 shows a heart 1 which contains an electrode 2 connectable by electrode means 3 to an adapter means 7 inside a pacemaker housing 4. Respiration monitoring means 5, either contained within or separate from the pacemaker housing 4, monitors the respiration cycle and produces a respiration cycle signal. The respiration cycle signal could be based on elapsed time since, for example, the detection of the start of inhalation (which corresponds to the beginning of a respiration cycle), and the elapsed time could therefore represent the stage in the respiration cycle that the stimulator user has reached (the momentary respiration cycle phase angle). An example of a time based system could be that respiration monitoring means 5 measures chest pressure which falls to a minimum when exhalation nears completion and starts to rise again when inhalation commences. Respiration monitoring means 5 can be programmed or contain circuitry to recognise this trough and produce a start of inhalation signal. Adapter means 7 can use this signal to calculate respiration rate and the stage in the respiration cycle that the stimulator user has reached. As described earlier, each stage in the respiration cycle that the stimulator user has reached has an associated stimulation impedance and, as described

later, adapter means 7 uses the stimulation impedance associated with the stage in the respiration cycle that the stimulator user has reached to determine the required stimulation energy.

It is also possible that the respiration cycle signal could be based on the measured momentary amplitude of a parameter which varies throughout the respiration cycle. In this case the respiration cycle signal would represent the amount of inhalation or exhalation. For example, in the case where respiration monitoring means 5 measures chest pressure, it can send an amplitude signal to adapter means 7, either when interrogated by adapter means 7 or continuously. Each chest pressure has an associated stimulation impedance and, in a similar manner to that described later for respiration cycle phase angle, adapter means 7 uses the associated stimulation impedance to determine the required stimulation energy. It is possible that a chest pressure amplitude has two associated stimulation impedances - the first one for inhalation and the second for exhalation. In this case adapter means 7 must analysis the amplitude signal to determine if the amplitude is increasing, which would represent inhalation, or decresing, which would represent exhalation.

There are many parameters which change in a repeatable manner during respiration and which can be used to represent the respiration cycle. A non-exhaustive list of such parameters includes lung volume, chest pressure, chest circumference, blood oxygen level, QRS signal amplitude, stimulation impedance and air velocity, but any parameter which has a consistent relationship with the respiration cycle can be used.

The respiration monitoring means 5 can be any suitable electrical transducer which can measure, for example, voltage, current, resistance or impedance, or any electro-mechanical transducer which can measure, for example, volume, pressure, strain, torque, bending, stretching, temperature or sound, or any suitable electro-chemical transducer which can measure, for example, the blood oxygen level.

During one complete respiration cycle, the parameter measured by respiration monitoring means 5 will vary from a maximum value, which could correspond to when inhalation stops, to a minimum value which could correspond to when exhalation stops. For the best possible accuracy in calculating the required stimulation energy, the parameter to be measured should be chosen such that the relationship between the amplitude of the chosen parameter and the amplitude of stimulation impedance should be consistent and repeatable, that is, if the stimulation impedance is recorded several times for a particular amplitude of the chosen parameter at a particular respiration rate, then the stimulation impedance should be approximately the same every time.

In a first embodiment of the invention, respiration monitoring means 5 is a ultra-sonic transducer, mounted in the patient chest, and it measures lung volume. Respiration monitoring means 5 is connected to adapter means 7 and sends an electrical signal which is proportional to the chest pressure to adapter means 7. Adapter means 7 processes the incoming signal to determine when the lung volume has reached a maximum and starts to decrease. This corresponds to the end of inhalation and the beginning of exhalation. By recording the time between consecutive maximum values, adapter means 7 can calculate respiration frequency (f breath) and hence calculate when the next respiration cycle should begin and what stage in the respiration cycle (the momentary respiration cycle phase angle) the patient is currently at.

In use, adapter means 7 determines the required stimulation pulsing rate (f pulse) in the manner which is usual for pacemakers and calculates when the next pulse is due. Before delivering or during delivery of the pulse, adapter means 7 determines the momentary respiration cycle phase angle. In order to reduce circuitry requirements, the respiration cycle can be divided into a number of sectors and a common stimulation energy requirement can be established for all the phase angles in a particular sector. For the sake of brevity in the following description the expression "phase angle" will be understood as also meaning "sector" as described above. Adapter means 7 then calculates or looks up in a look-up table the stimulation energy required for the momentary respiration cycle phase angle and commands the pulse generator 8 to deliver the required pulse. Adapter means 7 is connected to telemetry means 10 which enable adapter means 7 to be reprogrammed and to output data.

In a second embodiment of the invention, instead of calculating the momentary respiration cycle phase angle, the adapter means has a look-up table which contains a series of respiration monitoring means signal amplitudes, for example a series of lung volume amplitudes, and a corresponding series of required stimulation energies. Alternatively adapter means 7 can be programmed with an equation to calculate the stimulation required for a particular respiration monitoring means signal amplitude. When a stimulation pulse is to be delivered, the adapter means looks up or calculates the required stimulation pulse energy using the momentary amplitude of the respiration monitoring means signal and then commands pulse generator 8 to deliver the required pulse.

In a further embodiment of the invention, the evoked response is sensed and evaluated by measurement of a physiological parameter associated with the contraction by a contraction sensor 9, either contained within or separate from the pacemaker housing 4. If a contraction is sensed within the programmable or calculated response time period, that is, the period following a stimulation pulse in which a cardiac event initiated by the pulse would normally be expected to take place, then a counter for that stage in the respiration cycle is incremented by one. Each time there is a successful contraction on stimulation for that particular stage in the respi-

ration cycle the counter is incremented. After the counter reaches a predetermined number the stimulation energy value for that stage in the respiration cycle is reduced by a predetermined amount which can be a discrete value or a percentage of the actual stimulation energy, thus leading to a reduced energy consumption. The counter is subsequently reset to zero.

If, however, there is no contraction sensed then it is assumed that the stimulation energy was insufficient and the value in the look-up table for the stimulation energy required at that stage in the respiration cycle is incremented by an amount, which can be a discrete value or a percentage of the actual stimulation energy, and the counter for that stage in the respiration cycle is reset to zero. Thus each time no contraction is sensed for a particular stage in the respiration cycle, the stimulation pulse will be slightly more powerful the next time the same stage in the respiration cycle occurs and eventually the pulse will be sufficiently powerful to cause a contraction. It is conceivable that no contraction is sensed because of the sensor 9 malfunctioning or the contraction signal being masked by other signals. This could lead to a continuous, unnecessary incrementation in the stimulation energy which, apart from wasting energy, could lead to dangerous side-effects. Therefore it would be advisable for the adapter means 7 to set a maximum limit for the strength of a stimulation pulse at a given stage in the respiration cycle. Preferably said maximum limit would be made proportional to the stimulation energy calculated for one or more of the stages in the respiration cycle bordering said given stage in the respiration cycle.

In another embodiment of the invention, the respiration monitoring means only operates intermittently, for example for 1 or 2 minute every hour, or for 1 minute every day or any other period. The choice of the operating period depends, amongst others, on the symptoms of the patient, the length of time the pacemaker and leads have been implanted and the stability of the pacing system. During this operating period the stimulation impedance is measured in the following way: the output capacitors of pulse generator 8 are charged to their maximum voltage and when a stimulation pulse is required they are discharged for the maximum time programmed or calculated by adapter means 7. By measuring the voltage in the output capacitors after the pulse has been discharged it is possible to calculate the energy dissipated in the pulse and hence the stimulation impedance.

Adapter means 7 records each stimulation impedance against the stage in the respiration cycle or respiration signal amplitude. At the end of the operating period adapter means 7 determines the maximum stimulation impedance which usually occurs when lung volume is at its greatest amplitude. If, during the operating period, a stimulation impedance was measured at the time when lung volume was at its greatest amplitude, then this impedance value, if it is indeed the largest measured value, is henceforth used for calculating the required stimulation energy. If another measured stimulation impedance value is greater then that one is used instead. If, during the operating period, no stimulation impedance was measured at the time when lung volume was at its greatest amplitude, then a theoretical stimulation impedance for this time is calculated by statistical analysis of the recorded values. If this theoretical stimulation impedance is greater than any of the measured stimulation impedances then it is henceforth used for calculating the required stimulation energy. If another measured stimulation impedance value is greater than the theoretical stimulation impedance then that one is used instead. In this way the stimulation pulse energy should be always sufficient to achieve capture. Although the stimulation pulse energy will often be higher than necessary to achieve capture, it will still use less energy than the prior art devices and will not require as much computing power as the aforementioned embodiments.

The change in stimulation energy can be achieved by varying the pulse amplitude. A second method of varying stimulation energy is to vary the pulse duration. A further method of varying stimulation energy is to increase the number of pulses in a stimulation and to vary their number and/or amplitude and/or duration and/or timing.

Claims

1. A heart stimulator (4), for a human being, comprising a pulse generator (8) producing stimulation pulses, at least one electrode means (3) connectable to said pulse generator (8) and to the heart (1) for transmitting said pulses to said heart (1), characterised in that the heart stimulator (4) further comprises at least one respiration monitoring means (5) which monitors the respiration cycle of the human being for determining the stage in the respiration cycle that the human being has reached, and adapter means (7), connectable to said respiration monitoring means (5), for adapting the energy to be delivered in a stimulation pulse as a function of said stage in the respiration cycle.

2. A heart stimulator according to claim 1 characterised in that the respiration monitoring means (5) comprises one or more electrical and/or electro-mechanical and/or electro-chemical transducers (5).

3. A heart stimulator according to claim 1 or 2 characterised in that the respiration monitoring means (5) directly or indirectly measures the momentary lung volume of the human being.

4. A heart stimulator according to any of claims 1-3 characterised in that the respiration cycle is divided into two or more sectors, each of which have a dif-

ferent stimulation pulse energy requirement, and that said adapter means (7) receives a signal from the respiration monitoring means (5), determines which sector of the respiration cycle the human being is in and adapts the energy to be delivered in a stimulation pulse to take into account which respiration cycle sector the human being will be in at the time the pulse will be delivered.

5. A heart stimulator according to any of claims 1-4 characterised in that the stimulation pulse energy required for a sector is looked up in a table of values or is calculated.

6. A heart stimulator according to any of claims 1-5 characterised in that the amplitude of said stimulation pulse and/or the pulse duration of said stimulation pulse can be varied.

7. A heart stimulator according to any of claims 1-6 characterised in that said stimulation pulse comprises a stimulation complex of at least two pulses.

8. A heart stimulator according to claim 7 characterised in that the timing relation between the pulses and/or the amplitude of the pulses can be varied.

9. A heart stimulator according to any of the previous claims characterised in that it comprises sensor means (9) for sensing the evoked response.

10. A heart stimulator according to claim 9 characterised in that the stimulation pulse energy for a sector is increased by a pre-determined or programmable amount or percentage if no response is sensed in the response time period following a stimulation pulse sent during said sector.

11. A heart stimulator according to claims 9 or 10 characterised in that the stimulation pulse energy for a sector is decreased by a pre-determined or programmable amount or percentage of the actual stimulation pulse energy for said sector, if a response has been sensed in the response time period following a stimulation pulse being sent for all of a predetermined or programmable number of previous stimulations sent with a sector which is the same as said sector.

Fig.1

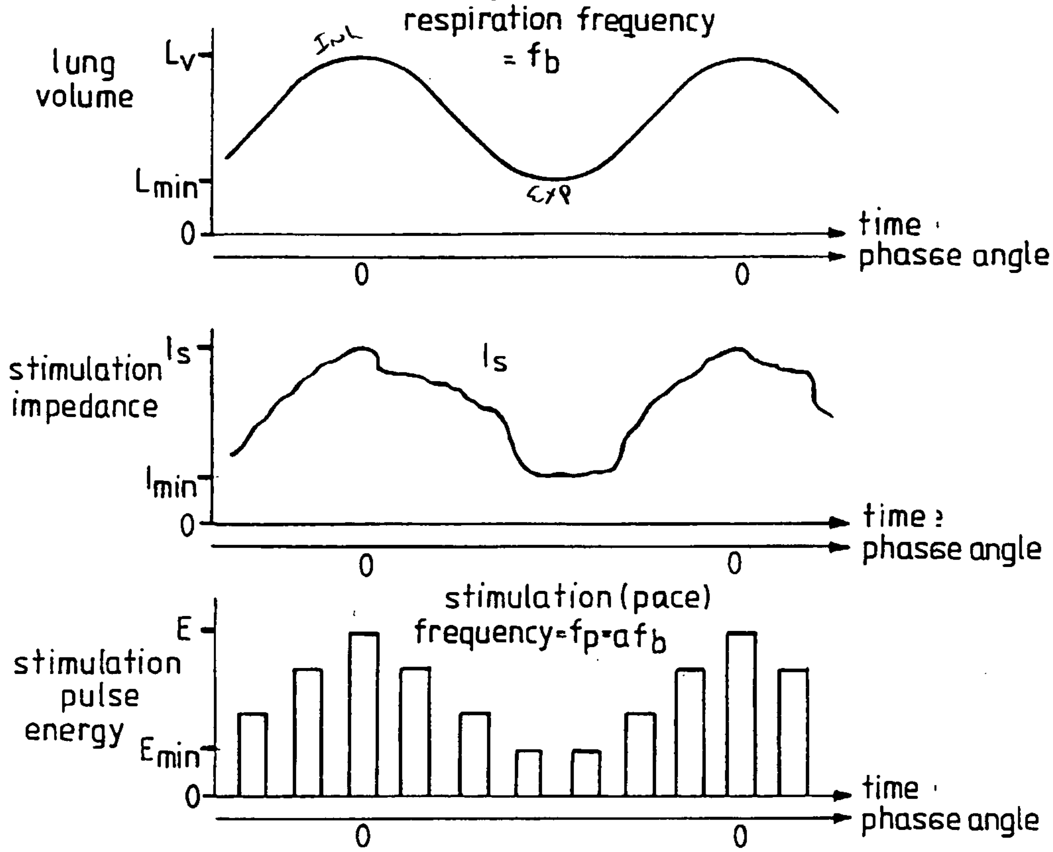
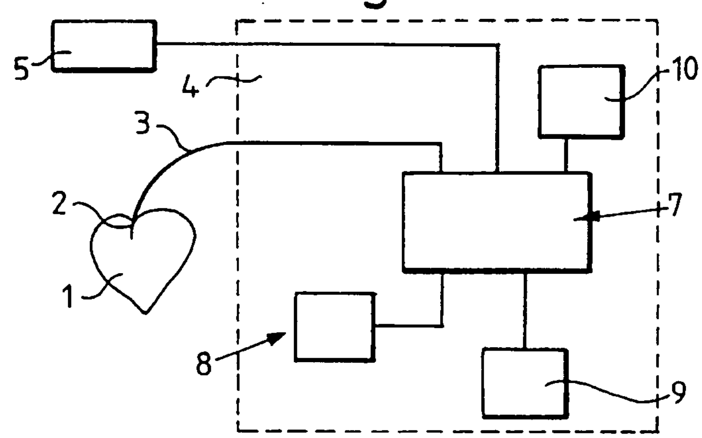

respiration frequency
= f_b
lung volume
L_v
L_{min}
0
time
phase angle
0
0
stimulation impedance
I_s
I_s
I_{min}
0
time
phase angle
0
0
stimulation (pace) frequency = f_p = $a f_b$
stimulation pulse energy
E
E_{min}
0
time
phase angle
0
0

Fig. 2


5
4
3
2
1
10
7
8
9

European Patent Office

EUROPEAN SEARCH REPORT

Application Number
EP 96 85 0112.2

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.6)
A	EP, A2, 0640359 (MEDTRONIC, INC.), 1 March 1995 (01.03.95) * abstract *	1	A61N 1/365
A	EP, A2, 0504935 (SIEMENS ELEMA AB), 23 September 1992 (23.09.92) * abstract *	1	
A	EP, A1, 0307093 (PACESETTER INFUSION LTD. TRADING AS-MINIMED TECHNOLOGIES), 15 March 1989 (15.03.89) * abstract *	1	
			TECHNICAL FIELDS SEARCHED (Int. Cl.6)
			A61N

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	4 October 1996	THOMAS SKAGERSTEN

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
Y : particularly relevant if combined with another document of the same category
A : technological background
O : non-written disclosure
P : intermidiate document

T : theory or principle underlying the invention
E : earlier patent document, but published on, or after the filing date
D : document cited in the application
L : document cited for other reasons

& : member of the same patent family, corresponding document